

141-446

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATION

In re Application of:

Unchalee Kositprapa et al.

Serial No.: 10/777,542

Group Art Unit: 1614

Filed: 02/12/2004

Examiner: Weddington, Kevin E.

For: **NOVEL PHARMACEUTICAL FORMULATION CONTAINING
A BIGUANIDE AND A THIAZOLINEDIONE DERIVATIVE**

New York, NY 10036
August 27, 2007

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

The following references are submitted by the applicant with the
accompanying Forms PTO/SB/08A.

Document
Designation

AA
U.S.P. 4,891,223

AB
U.S.P. 5,840,335

AC
U.S.P. 5,955,106

08/30/2007 WASFAW1 00000018 10777542
01 FC:1806 180.00 OP

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on August 27, 2007

Nicholas P. Chiara, Reg. No. 52,737

Document
Designation

AD
U.S.P. 5,965,584

AE
U.S.P. 6,099,859

AF
U.S.P. 6,153,632

AG
U.S.P. 6,166,042

AH
U.S.P. 6,166,043

AI
U.S.P. 6,172,090

AJ
U.S.P. 6,291,495

AK
U.S.P. 6,403,121

AL
U.S.P. 6,475,521

AM
U.S.P. 6,495,162

AN
U.S.P. 6,524,621

AO
U.S.P. 6,660,300

AP
U.S.P. 6,780,432

AQ
U.S.P. 6,790,459

AR
U.S.P. 6,866,866

Document
Designation

BA

U.S. Pub. 2004/0081697

BB

U.S. Pub. 2005/0074490

BC

U.S. Pub. 2006/0057202

BD

U.S. Pub. 2006/0141023

BE

U.S. Pub. 2006/0286168

CA

WO 2001/035941

Relates to a pharmaceutical composition comprising a thiazolidinedione and metformin HCl and a pharmaceutically acceptable carrier.

CB

WO 2004/067001

Relates to providing a process for producing pioglitazone HCl coated preparation.

CC

WO 2004/006921

Relates to providing a process for producing pioglitazone HCl coated preparation

In accordance with current United States Patent and Trademark Office practice no copies of the above listed United States Patents or published United States Applications are filed herewith. Full copies of non- United States Patent Documents are filed herewith. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

The fee of \$180.00 that is required for consideration of this Information Disclosure Statement is enclosed within. The Commissioner is hereby authorized to charge Deposit Account No. 08-1540 for any deficiency or credit any overpayment. A duplicate copy of this sheet is enclosed.

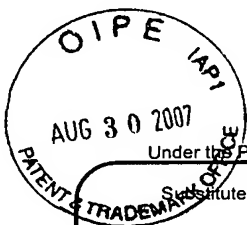
Respectfully submitted,



Nicholas P. Chiara
Reg. No. 52,737

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

| | |
|------------------------|----------------------|
| Application Number | 10/777,542 |
| Filing Date | February 12, 2004 |
| First Named Inventor | Kositprapa et al. |
| Art Unit | 1614 |
| Examiner Name | Weddington, Kevin E. |
| Attorney Docket Number | 141-446 |

Sheet 1 of 2

U. S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-----------------------|--------------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (if known) | | | |
| | AA | US- 4,891,223 | 01-02-1990 | Ambegaonkar et al. | |
| | AB | US- 5,840,335 | 11-24-1998 | Wenzel et al. | |
| | AC | US- 5,955,106 | 09-21-1999 | Moeckel et al. | |
| | AD | US- 5,965,584 | 10-12-1999 | Ikeda et al. | |
| | AE | US- 6,099,859 | 08-08-2000 | Cheng et al. | |
| | AF | US- 6,153,632 | 11-28-2000 | Rieveley | |
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| | AK | US- 6,403,121 | 06-11-2002 | Adjei et al. | |
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| | AN | US- 6,524,621 | 02-25-2003 | Adjei et al. | |
| | AO | US- 6,660,300 | 12-09-2003 | Timmins et al. | |
| | AP | US- 6,780,432 | 08-24-2004 | Cutie et al. | |
| | AQ | US- 6,790,459 | 09-14-2004 | Cheng et al. | |
| | AR | US- 6,866,866 | 03-15-2005 | Chen et al. | |
| | BA | US- 2004/0081697 | 04-29-2004 | Lewis et al. | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
|-----------------------|--------------------------|---|-----------------------------------|--|---|----------------|
| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
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Examiner
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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| Sheet | 2 | of | 2 |
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| First Named Inventor | Kositprapa et al. |
| Art Unit | 1614 |
| Examiner Name | Weddington, Kevin E. |
| Attorney Docket Number | 141-446 |

U. S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|---|--------------------------------|---|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | CA | WO 2001/35941 | 05-25-2001 | Lilliott et al. | | |
| | CB | WO 2004/067001 | 08-12-2004 | Ohkouchi et al. | | |
| | CC | WO 2004/006921 | 01-22-2004 | Koike et al. | | |
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|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

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